Manufacturing Online: A Case Study of Using an XML-based System to Create and Deliver Manufacturing Information

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Abstract
Guidant CPI, a manufacturer of medical devices, is significantly reducing its cost of manufacturing documentation while increasing the quality of information delivered to the assembly line by authoring in XML. Assembly instructions are delivered electronically via an intranet, which ensures that the assembly line is using current information. The intranet also allows electronic feedback from the line to the information authors, allowing continuous improvement. XML is a non-proprietary format with features which allow Guidant to easily and accurately reuse text objects and provide a dynamic view of information to the user.

Company Background
Guidant CPI is a manufacturer of cardiovascular medical devices such as heart pacemakers and defibrillators. 1998 sales were $1.9 billion. The company employs over 6,000 people. As a manufacturer of implantable medical devices, Guidant needs to provide products of the highest quality and also needs to document this quality to the proper regulatory authorities.

The Documentation Challenge
Documentation is created beginning in the design stage and is edited and supplemented to ensure that there are comprehensive descriptions and manufacturing instructions for each device.

In the manufacturing area, information was disseminated to the manufacturing floor on paper. Each product requires up to 3000 pages of documentation. Simply managing revisions for such a large volume of documentation required three full-time employees. Difficulties associated with document management sometimes was a source of increased costs and longer than optimum production cycle times.

The documentation process is complicated by the requirement that the product be manufactured in a clean room environment. This means that paper documents had to be laminated in plastic to prevent paper fibers from contaminating the device being manufactured.

Analysis of the manufacturing documentation revealed that it was composed of several different types of information:

- procedural
- policy
- decision making
- general
- frequency based (periodic)
- inspection
In addition, some of the information described the product, while other information described the processes associated with manufacturing and inspecting the product. Guidant set a goal of improving product quality and lowering costs by improving the manufacturing documentation process. Its objectives are to:
- decrease the number and rate of documentation defects,
- decrease manufacturing downtime spent waiting for distribution of documents,
- decrease the number of "documentation only" changes,
- decrease the document maintenance effort from 3 full-time employees to 0.5 full-time employee,
- consolidate to a single source of manufacturing information.

By meeting the above technical objectives, Guidant could help achieve better performance on its business objectives of:
- product compliance with specifications,
- manufacturing productivity,
- manufacturing process consistency,
- manufacturing uptime, and
- documentation maintenance costs.

**Manufacturing Online (MOL)**

Guidant's manufacturing organization conceived of "Manufacturing Online", also called MOL, as a vision which would allow them to meet their objectives. The idea is to eliminate paper by delivering electronic information directly to the manufacturing line.

In moving to a paperless environment, Guidant would have to overcome several challenges:

*Moving from a paper to an electronic culture.* The manufacturing workers at Guidant are accustomed to reading paper documentation and providing written feedback. Would they be willing and able to adapt to reading information off a monitor and interacting with the machine in order to provide feedback?

*Restructuring documentation for online viewing.* Manufacturing documentation is organized and styled for effective delivery on paper. A different viewing medium would be more effective if the documentation structure and style is chosen for that specific medium. This might mean rewriting legacy information and developing new processes and styles.

*Work area space / Hardware selection.* The physical layout of the assembly stations must be considered. Would there be sufficient room for the Monitor? Could the monitor and keyboard be placed in an ergonomically correct position for the assembly technician? What type of hardware would be appropriate?

*Computer skill levels.* Assembly technicians were not required to have any experience in using a computer. Would they be able to learn how to operate the computer?

**Requirements**

For electronic document delivery a web-based or otherwise known as an intranet system was seen as cost effective given the present state of this technology. In a web-based information delivery system links to existing systems can easily be built. Standard
browsers provide a familiar, consistent, and easy to understand user interface. Proper design of the information presentation can provide further context-sensitive cues to the proper information.

Electronic, hyperlinked information delivery makes it possible to provide supplementary information in a way that was not practical with paper-based information delivery. Hypertext links provide quick access to and from supplementary pages. Graphics can be more easily incorporated and maintained in documentation. Annotations such as "tips and techniques" and glossaries can be easily accessed.

Guidant has manufacturing facilities at various international locations. Manufacturing Online will be deployed at manufacturing lines in Saint Paul, Puerto Rico, and in Ireland. Electronic delivery of manufacturing information is especially advantageous when they need to be delivered to remote locations.

In order to make such a system practical to implement and cost-effective to maintain it was decided that consistent, industry accepted standards should be used. Yet it should be possible to flexibly use the standards to meet the needs of the project.

The initial system would need to display a list of components, equipment, and supplies, training information, and build instructions. The instructions should be appropriate for the given product and the equipment available for its assembly.

Why XML?

Guidant first found about XML while searching the Internet for technologies which could be used for MOL -- so the project vision preceded the decision to use XML. XML was chosen because it is tool and vendor independent, it is an industry standard, the content can be kept independent of the presentation (style), and it allowed for the possibility of dynamic document delivery.

Guidant contacted Arbortext because the Arbortext name was always connected with XML, and Arbortext's vision for XML was in line with Guidant's vision for XML.

Arbortext Epic

Epic is based on XML and maintains content in this industry standard, non-proprietary format. From XML, Epic includes all the tools needed to publish to multiple formats -- including the web and Postscript -- automatically. No other software needs to be integrated for multiple outputs.

Epic also recognizes the existence of tiers of users. Full time writers use a full function "Author" seat. Engineers and other occasional contributors to documentation can use a reduced function editor with a simplified interface.

Epic has a feedback function, which allows information to flow from the information user -- or reader -- back to the documentation supplier. Guidant will use this function to gather user input on the documentation. The operators often can contribute significant value to manufacturing documents but it is difficult to collect this feedback in a traditional paper-based environment. By making it easy to provide feedback, Guidant hopes that engineers, writers, and users will become more closely tied together and create better documents.

Furthermore, Epic includes a rich command language and tools for customization, so the product can closely meet the requirements of MOL.
Guidant Customizations of Epic

Guidant is using the XML version of the DocBook DTD which is the standard DTD for Epic. However some minor changes were made to the DTD. The formats to be published to are print, Postscript, asp, and HTML. A redlining function was added to Epic to enable detailed comment on authored material. The redlined text can be viewed in browsers, as well as in the authoring tool. A query function was added which allows queries to the BOM and to appendix tables. These queries can be run dynamically. A custom interface for these queries has been developed. Templates were created to make it easier for authors to create new documents. Print formatting was modified to conform to Guidant needs.

Web Site Design

The MOL web site was designed to incorporate the Epic authored material. Querying uses the transformations from Epic. Considerable care was taken with design of the user interface so that documents would be presented in the most user-friendly and accessible manner. Guidant is using Epic's personalization capabilities to present different views of the information based on a production worker's past experience building the product, the specific equipment available at the worker's workstation, and the specific product s/he is building.

Guidant is primarily using Epic to create manufacturing instructions. Wherever specific parts are mentioned, they are filled in automatically at run-time. That means that the bill of materials can be changed without changing the documentation. It also means that a single set of manufacturing instructions can be used for a variety of products.

Current Project Status

The MOL system is now being used on three small manufacturing lines. Extending deployment to all of manufacturing is regulated by the availability of resources. There are no technical limitations to the installation size. This system is scaleable to far beyond the needs of Guidant.

So far, the system meets the original project goals and vision. It is being well-received by users. The most common comment is "When can everyone have this system?"

Future Plans

The current system uses the file system for storing documents and document objects. Guidant plans to Integrate Epic with their engineering product data management (PDM) system, as well as with a document management system (DMS).

Right now the system converts the native XML content to HTML via a stylesheet for presentation in the browser. This is done to make the content accessible via a wide range of browser versions. Guidant has control over the browsers used for MOL. Therefore, they hope to provide native XML directly to the browser in the future.

Guidant also plans on utilizing additional XML related standards in MOL -- such as XSL, Xlink, and Xpointer.

Guidant plans on continually adding functionality and information sources to the MOL web site.
Other users at Guidant
Through experience with the MOL project, Guidant has learned how XML and Epic might be useful for other functional areas in the company. For example:
- System Asset Management for requirements tracing
- Test Engineering for transferring data from testing stations to various databases

Conclusion
The XML-based Manufacturing Online project is expected to eventually save 20% to 30% of the costs of manufacturing document production at Guidant. Additionally, the company expects that by improving its employees' ability to get the information they need efficiently, it could improve overall product time-to-market from two to five percent by lowering production time.

Figure 1: Basic Arbortext Epic Configuration